***Final Progress Report Summary***

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# Design, evaluation, and validation of a next-generation inhalable aerosol sampler

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***Abstract:***

## *Design, evaluation, and validation of a next-generation inhalable aerosol sampler*

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This work proposed to develop and test the performance of a low-cost, easy to use, disposable sampler to measure personal exposures to inhalable aerosols in the workplace. To improve the likelihood of future adoption by exposure assessors, the sampler incorporated a redesign of the inlet cap of the 37-mm sampling cassette, the most commonly used particle sampler in the U.S. The sampler inlet was designed to aspirate large particles with efficiency to match the international performance criterion for inhalable aerosol sampling. As such, the sampler was designed to capture particles with the same efficiency as a worker's mouth and nose. This research: (a) used computational fluid dynamics modeling tools to investigate how inlet geometries affect sampling efficiency, to optimize the sampler inlet, and to estimate an orientation-averaged sampling efficiency for the prototype sampler(s) to compare to the inhalable criterion; (b) investigated the sampling efficiency of the prototype sampler in a low-velocity wind tunnel and a calm-air chamber to quantify accuracy, precision, linearity, and internal losses, in controlled environments; and (c) field tested and validated the sampler performance in three manufacturing settings and compared the sampling efficiencies to existing devices. The design and optimization phase of this project incorporated computational fluid dynamics modeling to investigate the impact of seven inlet shapes and three inlet diameters on the sampling efficiency of particles across the inhalable range, namely up to 100 μm. This research identified that sampler inlets with a 15-mm opening, either with a flat surface or with a small protrusion adjacent this opening, provided the best agreement with the low-flow inhalable particulate mass sampling criterion. Based on simulations, prototypes were made to include a rigid, disposable outer structure with a lightweight internal capsule protruding through the sampler exterior to capture all particles entering into the sampler for subsequent analysis. Wind tunnel testing demonstrated that sampler performance matched closely to the current state-of-the-art (IOM inhalable aerosol sampler) and to proposed criteria for low-velocity particle inhalability curves. Sampling efficiency was not affected by the flow rate through the sampler, over a range of 2 to 10 L/min. Field testing included: (a) area monitoring in swine production, (b) personal monitoring in multiple metals operations processes including foundry and metal refineries, and (c) personal sampling in dairy parlors. In the dairy study, both exposure indicators of respiratory inflammation in the workers were examined to evaluate whether exposures measured with the new inhalable sampler improve the measurements of association of health outcomes. The new sampler demonstrated a higher mass capture rate than the existing 37-mm cassette and agreement with the IOM device. End-of-shift biomarkers of upper-respiratory inflammation in dairy workers were also associated with exposure measures made using the new sampler. The long-term outcome of this project includes the advancement of a new device to improve exposure assessment evaluations. By increasing the adoption of physiologically-relevant exposure assessment tools, data-driven risk-based exposure limits for hazardous aerosols can be improved to protect worker health.

# Section 1.

# Design, evaluation, and validation of a next-generation inhalable aerosol sampler

## Significant or Key Findings

Key Finding 1: This project proved that a low-cost, disposable sampler for inhalable aerosol could be developed that meets the needs of the industrial hygiene community.

Key Finding 2: Both computational modeling and experimental evidence confirmed that the new sampler could meet desired performance metrics at flow rates of 2 and 10 L/min. This finding means that the new sampler is versatile to meet the analytic detection limits in a diverse set of environments.

Key Finding 3: Laboratory testing demonstrated that the new sampler matches closely to the performance of current ‘gold-standard’ methods while also adhering to published performance criteria for inhalable aerosol sampling.

Key Finding 4: Multiple field tests of the new sampler, when co-located with existing standard methods, confirmed the results of the laboratory testing while also demonstrating improvements in the new technology related to cost, versatility, and ease-of-use.

Key Finding 5: Markers of upper respiratory inflammation in dairy workers were associated with exposures to organic dusts and endotoxin when exposures were assessed using the new sampler.

## Translation of Findings

This project developed and validated a new tool for assessing exposures to inhalable aerosol hazards in the workplace. This tool offers advantages over the current state-of-the-art by being inexpensive (disposable) and simple to operate, while also having performance that meets or exceeds current technologies that are standard practice in the field. These findings were demonstrated in real-world settings (agriculture, mining, and manufacturing sectors). The success of this project is also evident through the rapid uptake and commercialization of the technology developed here: Access Sensor Technologies, LLC, has licensed this technology and has already developed a commercial prototype for initial sales and distribution. Thus, this project was able to achieve research-to-practice success in a relatively short span.

Further validation of the technology was demonstrated by using it to assess organic dust exposures among dairy workers and the association between these exposures and markers of upper respiratory inflammation among this population. Exposures to high levels of organic dusts are prevalent among these workers and these exposures are associated with increases in markers of upper respiratory inflammation. The biologic plausibility of this exposure-response hypothesis was confirmed by comparing exposure measurements made with the new technology to the older the 37-mm closed face cassette sampler (a device that is known to under-sample large dust particles apt to deposit in the human nose and throat). Thus, our findings suggest that adoption of the new technology will provide more accurate and precise measurements of worker exposure that, in turn, will help occupational health professionals to identify and mitigate workplace aerosol hazards.

## Research Outcomes / Impact

Potential outcomes: This project developed new technology that can lead to more comprehensive and representative assessment of workplace aerosol hazards. The adoption of this technology should improve our ability to recognize and control dust exposures in the workplace.

## Section 2 - Scientific Report

## Design, evaluation, and validation of a next-generation inhalable aerosol sampler

## Background

Inhalable dust exposure contributes substantially to the U.S. (and global) occupational disease burden. Globally, respiratory diseases account for approximately 50% of all occupationally-related mortalities (425,000 deaths/year worldwide). In the U.S. alone, the cost burden of these diseases has been estimated at $7 billion/year. Exposure to inhalable aerosols has been associated with both clinical diagnosis and sub-clinical markers of respiratory disease in every NORA sector. In 2011, the British Institute for Occupational Medicine issued a position statement that the current limit value for inhalable dust (10 $mg/m^3$ as an 8-hr TWA, similar in nature to the ACGIH TLV for "Particles Not Otherwise Specified, Inhalable") was not protective of worker health. This position statement was issued due to recent evidence of respiratory disease in workers exposed to coal dust, silica, and other chemically-inert aerosols at levels below the current limit.

'Inhalable' dust sampling, based on internationally accepted criteria, is more physiologically relevant than 'total' dust sampling (37-mm cassette) required for use by the U.S. OSHA. The inhalable convention requires nearly 100% sampling efficiency for smaller particles (<10 μm) with decreased efficiency with increasing particles sizes, plateauing at 50% efficiency for particles between 50 and 100 μm. A biologically-relevant estimate of *dose* (by virtue of exposure measurement) is vital to provide meaningful results when attempting to correlate exposure and disease. Due to variability in human respiration (*e.g.*, tidal volume), an appropriate and conservative measure of dose would be the amount of airborne material that can enter into the nose and/or mouth during breathing, as opposed to the 'total' dust measure that is commonly used today.

Existing technologies for inhalable aerosol exposure assessment (*i.e.*, the IOM and Button samplers) have serious shortcomings; the developing scientific opinion indicates that a new sampler is needed. Existing inhalable samplers were designed to match to a 'particle inhalablility criterion' that is now considered inadequate. This (outdated) inhalability criterion curve has recently been called into question for its representativeness under typical low-velocity/calm-air conditions and in light of recent data on the effects of convective air motion due to human physiology. These data (reported by the *developers* of the inhalability criterion) suggest that even the state-of-the-art IOM and Button samplers not capturing a physiologically-relevant sample due in part to invalid assumptions made over 25 years ago.

Given the burden of disease associated with chronic workplace exposures to particles across the entire size range of inhalable particles, a need for a new generation of personal, inhalable dust samplers capable of capturing physiologically relevant sample is needed. To be widely adopted, they must meet sampling efficiency characteristics and be: low-cost, easy to use, and disposable.

## Aims

The *long-term goal* of this project is to increase the use of inhalable aerosol samplers among U.S. occupational health practitioners. Achieving this goal will provide better knowledge about exposure, risk, and the relationships between exposure and disease. Such knowledge, in turn, will support improved exposure limit development and, ultimately, the reduction of occupational illnesses. The *objective* of this project is to develop and demonstrate a low-cost sampler that integrates into the occupational hygienist's sampling paradigm while providing physiologically-relevant estimates of inhaled aerosol. *The central hypothesis of this work is that the inlet to the standard 37-mm closed face*

*cassette (CFC) can be modified to perform with the same efficiency as human particulate aspiration in low-wind environments.* This project had three specific aims:

Aim #1: Design and optimize an improved inhalable aerosol sampler for operation at 10 L/min flow
Aim #2: Evaluate sampler performance in the laboratory.
Aim #3: Validate sampler performance during three intensive field campaigns.

In meeting these, we have developed and demonstrated a high-flow inhalable aerosol sampler that is relevant for quantifying exposures in low-velocity environments and that is inexpensive, easy to use, and disposable, improving the likelihood of widespread adoption by occupational health practitioners. By increasing the adoption of physiologically-relevant exposure assessment tools, data-driven risk-based exposure limits for hazardous aerosols can be improved, and exposure control efforts can be targeted to reduce exposures in a more efficient, cost-effective manner, ultimately protecting worker health.

## Methodology

### Aim 1: Design and Optimize Sampler

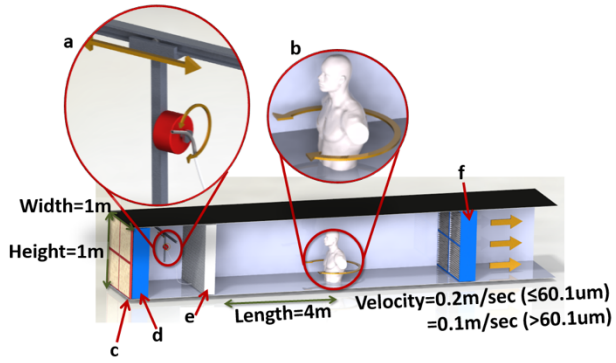
The preliminary design and optimization occurred in a virtual environment, using computational fluid dynamics modifications to simulate airflow and particle transport into digitized modifications of a standard two-piece 37-mm closed face cassette (CFC). We simulated seven entry shapes combined with three sampler inlet sizes (12, 20, 25 mm) and examined their effect on the collection efficiencies of these samplers for particles ranging from 1 to 116 μm in aerodynamic diameter. The simulated samplers were positioned on a simplified torso at first, for simulation efficiency. Air velocities of 0.2 m/s were evaluated for all conditions, with sensitivity analyses at 0.1 m/s and 0.4 m/s velocities. Particle collection efficiency was evaluated with simulated samplers operating at 10 L/min for all geometries, with some conditions evaluated at 8 L/min to evaluate design sensitivity to sub-optimal pump operation in the field. Following the comprehensive assessment of the seven face shapes and three inlet openings, the optimized designs were evaluated at multiple orientations relative to the slow moving freestream in order to assess the performance of three sampler designs to compare the omnidirectional sampling efficiencies to sampling criterion.

To assess omnidirectional performances of samplers, wind tunnel studies rely on rotating samplers positioned on mannequins. For these computer simulations, digitized samplers were positioned on humanoid geometries to represent the more complex airflow and particle trajectories associated with slow-moving air around humans. We modeled flow around a humanoid mannequin that was fitted with either the Thin-15, Flat- 15, or Perimeter-15 inlet geometries, mounted near the right shoulder and simulated particle collection by the samplers over 12 orientations (0, 15, 30, 60, 90, 135, 180, 225, 270, 300, 330, and 345$^{o}$ relative to the oncoming wind). Freestream velocity (0.2 m/s) and sampler flowrate (10 L/min) were matched to work being performed in the wind tunnel (Aim 2).

### Aim 2: Evaluate Sampler Performance in the Laboratory

Particle aspiration and sampling efficiencies of the new sampler were evaluated at the Rocky Mountain Center for Occupational & Environmental Health wind tunnel lab at the University of Utah in Salt Lake City, UT. Sampler efficiency was tested in a low velocity wind tunnel equipped with a rotating manikin matching average human dimensions. Two wind speeds (typical for indoor environments) were tested: 0.1 and 0.2 m/s. Narrowly-graded powders of fused alumina in seven size ranges were used as challenge aerosols to cover the entire inhalable size range (0-100 μm). The prototype sampler was evaluated relative to the proposed low-wind-speed inhalabilty curve and also relative to the Institute for Occupational Medicine (IOM) sampler for inhalable aerosol mass. Sampler

efficiency was calculated from the ratio of concentration measured by the sampler to the freestream concentration as estimated from the isokinetic reference probe. Efficiency measurements for each alumina particle size range used the average of all instruments and test replicates using a pooled estimate of variance. Gravimetric filter capsule stability was also evaluated, since the capsule was solvent-welded to the filter surface. An image of the wind tunnel test facility is shown below (L'Orange et al., 2016).



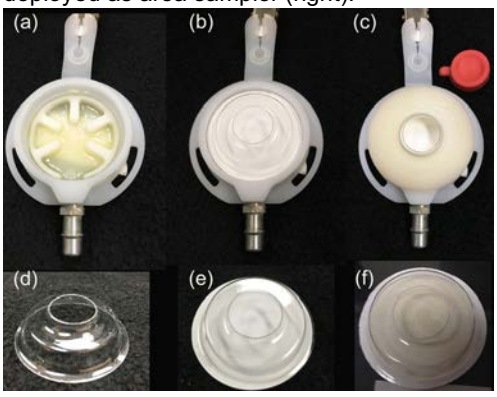

Low velocity wind tunnel used for testing the new sampler. The tunnel was operated at 0.1 m/sec and 0.2 m/sec (particle size dependent), with particles distributed using a TOPAS Solid Aerosol Generator 410. (a) Particles between 9.5 µm and 60.1 µm were distributed through a dispersion tube that transverse the width of the tunnel and oscillated through a 45º arc. Larger particles were dispersed from the top of the wind tunnel. (b) Samplers were attached to the lapel of a manikin that rotated clockwise 360º and then 360º degrees counterclockwise. The manikin was 4 m from the flow conditioner. The tunnel includes (c) pre-filters, (d) HEPA filters, (e) a flow conditioner, and (f) post-filters.

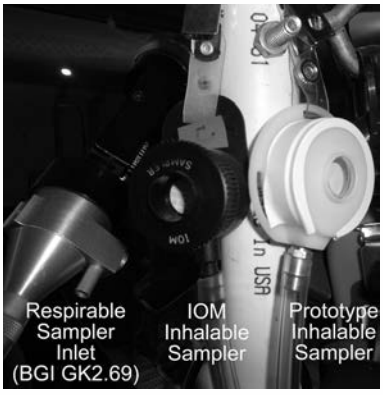
## Aim 3: Validate Sampler Performance in the Field

*Iowa #1: Swine Barn Area Sampling (Anthony et al., 2016)*

In 2014-2015, a field study that was measuring respirable and inhalable dust concentrations in a swine production building incorporated the prototype sampler into their sampling plan to allow for comparison between traditional (IOM) inhalable concentration measures. This was the first field deployment of the prototype sampler (original prototype design, Figure 1), relying on deploying monitors as area samplers. Dust samples were collected over 24-hour periods at three fixed locations in the test room. Monitor inlets were positioned at breathing zone height (1.5 m), collocated as close to one another as practical. Respirable dust was collected onto 5 µm PVC filters using cyclones (BGI GK2.69) positioned on direct reading equipment (pDR-1200, Thermo-Electron Corp.). Sampling pumps (PCXR4, SKC, Inc.) pulled air through the cyclone-pDR at 4.2 L/min. Inhalable dust was collected at matched locations using both the IOM (5 µm PVC filters) sampling at 2 L/min using PCXR4 pumps (SKC, Inc.) and the prototype low-cost inhalable dust sampler (2 µm PTFE filter with PMP ring) using a combination of Leland Legacy and BGI 400 pumps to achieve the high flow rate. The study attempted to collect 57 collocated sets of samples. Inhalable dust (gravimetric) and endotoxin (Pyrogene™ assay) concentrations were compared between samplers.

Figure 1: Prototype design as deployed in swine production study (left) and deployed as area sampler (right).



*Utah #1: Smelter Operation (Shahan 2016; Manning 2017)*

The second iteration of the prototype design was deployed at a smelter operation (Figure 2). The filter support area was modified from the slots (Figure 1(a)) to a more solid platform with equally spaced holes to distribute airflow through the sampler filter. This prototype version did not require the use of a cellulose backup pad, which reduced the pressure drop through the sampler.

Figure 2: Second iteration of prototype high flow sampler showing components (left) and fully assembled (right), deployed at smelter operations.

A total of 35 side-by-side personal samples were collected from furnace room workers at a metal smelter during two winter months (Figure 3). Jobs included: flash smelting tappers, boiler workers, flash converting tappers, and measurers. A Leland Legacy sampling pump was able to achieve 10 L/min through the prototype (without backup pad), and the IOM sampler relied on an SKC XR5000 pump to achieve 2 L/min flow. A chi-square test was used to examine both samplers' ability to meet the limit of detection (LoD) and limit of quantitation (LoQ) for beryllium, chromium, manganese, and nickel. Direct comparisons were made between concentrations from both samplers for inhalable dust (gravimetric) and a combination of arsenic, cadmium, copper and lead, exploring mean biases.

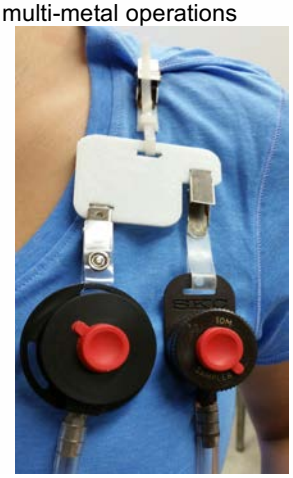
Figure 3: Sampler assembly used for smelter study

*Iowa #2: Metals Operations (Tompkins, 2017)*

This study used a third fabrication of the prototype sampler, which was black in color but had similar filter platform to the previous version used in the Smelter Worker evaluation, requiring no backup pad to support the filter/capsule.

For this evaluation, both area and personal samples were collected using the IOM and prototype samplers in occupational settings known to have metal aerosol exposures. MCE filters were used in each sampler to facilitate metals analysis, which prevented gravimetric analyses due to instability of the filter media. Thirty-two paired IOM and prototype samples were used to measure airborne metal concentrations at 17 fixed areas and 15 personal breathing zones (Figure 4). Monitoring was conducted at a variety of indoor operations to examine sampler performance for multiple operations which differed in metal composition and in anticipated size distribution of generated aerosols. These production processes occurred in: fabrication studio, heavy equipment manufacturing, foundry, shooting range. Monitoring was conducted on or near workers performing tasks that could generate metallic aerosols, specifically: welding (6), grinding (10), soldering (4), pouring (4), sawing (2), tending (2), molding (1), coring (1), degating (1), and shooting (1). The team qualitatively determined the predominant size of particle in each sampling event, categorizing the following as "small": welding, soldering, pouring, tending, and shooting. All other processes were presumed to include particles larger than 10 μm and were categorized for post-hoc performance tests by particle size category.

Figure 4: Example positioning of prototype (left) and IOM (right) for personal exposure assessment measurements in multi-metal operations



Samples were analyzed using a modified method NIOSH 7300 to quantify 15 metals: aluminum, arsenic, beryllium, cadmium, calcium, chromium, copper, iron, lead, manganese, nickel, selenium, sodium, silver, and zinc. Sample analysis used the same analytical lab as was used for the smelter worker study. Data analysis compared both individual metal concentrations and total metal mass concentration detected on paired samplers, where total metal mass concentration was computed using the mass of each positively quantified (>LOD and LOQ) metal reported for each sample. Wilcoxon rank-sum analyses for two-sided tests compared individual metal concentrations between both samplers. Linear regression between IOM and prototype metal concentrations were performed to examine the relationship between samplers over all samples and for data separated by type (area, personal) and qualitative anticipated particle size (small vs large) based on operation.

*CSU #1: Colorado Dairies*

Personal exposure sampling at four Colorado dairies took place from Spring through fall of 2015. The purpose of this field study was to evaluate the hypothesis that measures of upper respiratory inflammation (e.g., IL-6, TNF-$\alpha$) and pulmonary function (e.g., FVC, FEV1) will be more strongly associated with the inhalable exposure measures as compared to measures made using the traditional CFC.

This field study also used the third fabrication of the prototype sampler (similar to Iowa#2), requiring no backup pad to support the filter/capsule. Several other important differences occurred between the CSU dairy study and the Iowa swine barn study (i.e., Iowa#1 above). First, the reference sampler was the 37-mm closed face cassette (a common choice among industrial hygienists due to its simplicity and low cost). Second, in addition to exposure, we assessed markers of upper respiratory inflammation at the end of each work shift using a nasal lavage followed by sample analysis using an enzyme-linked immunosorbent assay technique.

A total of 37 participants were recruited into the study with each participant completing between one and eight repeated measures (i.e., multiple shifts across consecutive workdays). Personal exposures were assayed for mass (via standard gravimetric analysis) and endotoxin levels (via the recombinant factor C assay). All samples were collected onto Teflon-coated glass fiber filters (Pallflex Fiberfilm T60A20). Sample flowrates were checked pre/post sampling using a calibrated flowmeter. Nasal lavage samples were assayed using a Luminex bead assay for the following pro-inflammatory cytokines: IL-6, IL-8, TNF-$\alpha$, IL-1$\beta$, and IFN-$\gamma$. Participants were also assessed for cross-shift changes in pulmonary function using American Thoracic Society (ATS)-approved methods.

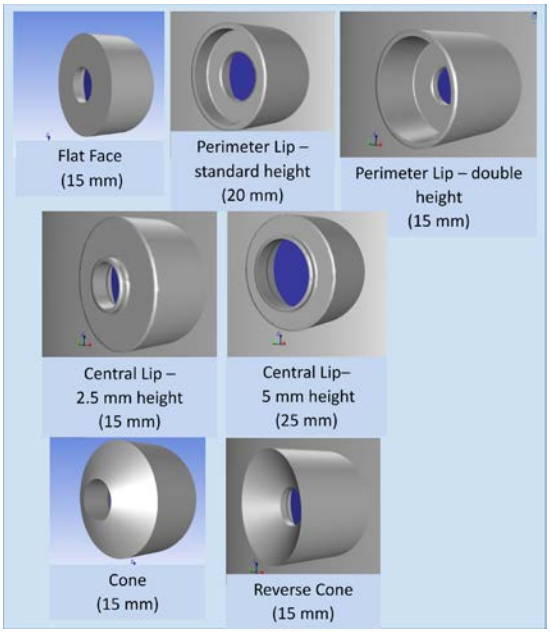
An intake questionnaire was completed prior to the sampling campaign to collect information on individual demographic and lifestyle factors such as age, socioeconomic status, race, ethnicity, tobacco and alcohol consumption, medication use, residence on a farm, and exposure to livestock and animals outside of the workplace. Job and workplace characteristics were also ascertained such as job title, work duration, potential exposure to visible dust, metal fumes, gases/vapors, pesticide use, respirator use, and respiratory health (asthma, allergies, chronic bronchitis, emphysema, lung cancer, cold or flu symptoms, sinus problems, pneumonia, anosmia). Daily questionnaires were completed before and after each participant's work shift in order to obtain information on the participants' respiratory health prior to and after the work shift. The daily questionnaires used questions from the ATS standardized instrument to evaluate chronic respiratory symptoms such as cough, phlegm, wheezing, shortness of breath, nasal irritation, fever or chills.

Linear mixed models were used to analyze the effect of sampler type, dairy, and season on cytokine response and to determine which sampler (prototpye or 37-mm CFC) predicted stronger, more precise associations between exposure and indicators of upper respiratory inflammation. To account for the repeated nature of the study design, a subject identifier was included as a random intercept.

## Results and Discussion

### Aim 1: Design and Optimize Sampler

Figure 5: Illustrations of shape (opening diameter) used in computational fluid dynamic simulations




Seven shapes were examined, as illustrated in Figure 5. The Perimeter Lip configuration matched the dimensions of the current 37-mm closed face cassette (CFC) sampler, although with the inlet changed to a larger pore than the current 4 mm opening (20 mm shown). Changes to this shape included: removing this perimeter lip (flat face), expanding the perimeter lip (double height), and changing its position from the edge to adjacent to the opening (central lip, with two heights). The Cone and Reversed cone were the greatest departure from the CFC.

After assessing convergence of the fluid field solutions surrounding the sampler, particle simulations were conducted to identify the critical area upstream of the sampler, through which all released particles would terminate in the sampler opening (Anthony and Flynn, 2006). Figure 6 summarizes the results of the forward-facing sampler efficiencies, with the Flat sampler having 15 mm opening shown in each comparison. Fig. 6(a) identified little difference between the flat and those with the protruding lip located adjacent to the sampler entry. Fig. 6(b) illustrates how the cone shape enhances the sampler collection efficiency for larger particles, and the reverse cone substantially reduces this collection efficiency. The effect of the protrusion around the edge of the sampler is illustrated in Fig. 6(c), which shows that the "37-mm CFC" with a centrally located 15 mm hole (Perimeter Lip) provides similar collection efficiency to the reverse cone. Further, both of these geometries resulted in substantially lower collection efficiencies than the flat entry shape. Finally, extending the perimeter lip causes substantial reduction in sampling efficiency for particles with aerodynamic diameters as small as 25 μm.

Figure 6: Facing-the-wind (0°) sampler efficiency results

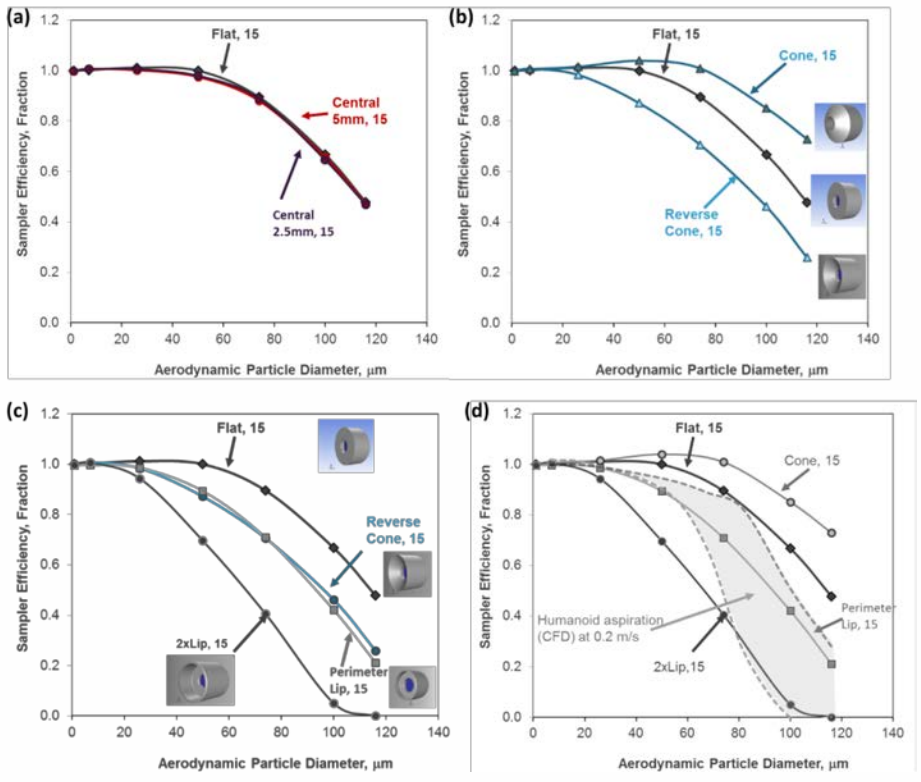



Figure 6(d) compares the range of sampler efficiencies to human aspiration simulations at matched freestream velocities (0.2 m/s), which illustrates that the Perimeter Lip estimates are within the range of human aspiration and that the Flat and

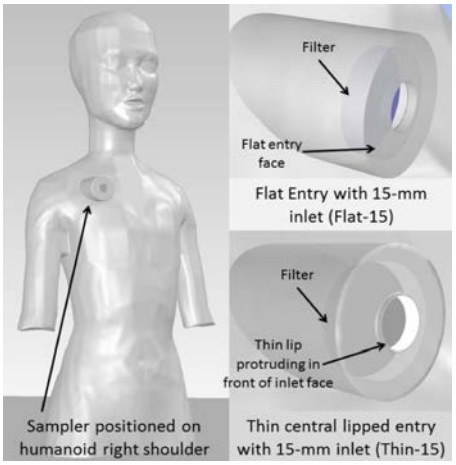
Central Lip samplers collect at the higher end of the human aspiration efficiency estimates.

Additional analyses of these simulations identified the following, which was important to the final design of the low-cost sampler:

- Increasing the opening size of the sampler (from 15 mm to 20 or 25 mm) increased the collection efficiency for particles larger than 100 μm, the theoretical upper limit for the inhalable criterion. Retaining the 15 mm opening is preferred.
- Shorter protrusion heights for lips may result in sampling efficiencies being sensitive to sampler flow rate, so the flat entry may not be preferred over a 5 mm thin central lip.
- Among all sampler designs, sampling efficiencies differed most predominantly for larger particles.

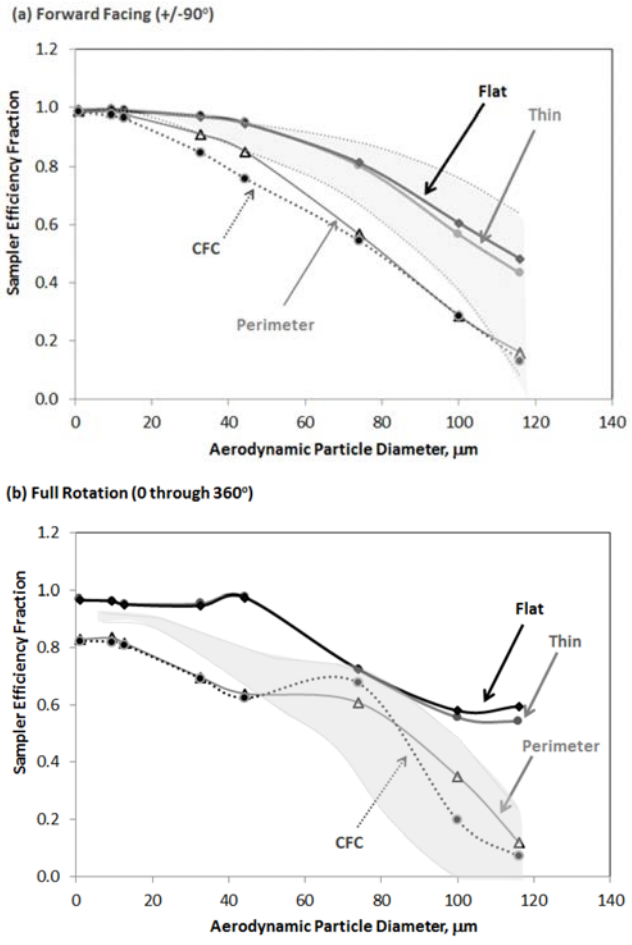
Additional details are given in Anthony *et al.* 2016.

Figure 7: Geometry for omnidirectional simulations




Simulations for three samplers (flat, thin and perimeter), each with 15-mm openings, were advanced to be examined in omnidirectional setting, using a more realistic humanoid torso (Figure 7). In addition, a simulated standard 37-mm CFC was generated and included in this analysis. Figure 8 presents orientation-averaged sampling efficiencies, again with the shaded area illustrating equivalent humanoid particle aspiration efficiency curve for the matched 0.2 m/s freestream condition. Similar to the previous investigations on a simpler "torso" shape, the flat and thin samplers performed nearly identically across the range of inhalable particle sizes. Across the forward facing direction (from +90 to -90 degrees relative to the oncoming wind), the flat and thin samplers perform within the simulated human aspiration efficiency envelope, while both the CFC and perimeter sampler under-sampling for particles 30 μm and larger (Fig. 8(a)). However, across full rotation (360°, Fig. 8(b)) relative to the predominating low-velocity wind, the flat and thin sampler tended to oversample particles relative to an aspirating human, with divergence for the large particles indicating a substantial oversampling might occur in the back-to-the wind orientation.

Figure 8: Comparison of average sampler efficiencies for humanoid-mounted samplers rotated through (a) forward facing and (b) omni-directional orientations. Shaded area represents the range of human aspiration efficiencies from CFD simulations, matched in orientation and 0.2 m/s freestream velocity.




Results from the first stage of this aim were used to select the design features for the low cost, high flowrate prototype sampler. The prototype that was fabricated had a flat-faced sampler inlet cap that incorporated an internal capsule that protrudes from the opening, similar to the simulated thin-15 design.

Video files were generated from the particle simulations and incorporated into presentations that have been used to demonstrate and educate concepts of inhalable particles,

with the intent of improving the profession's understanding of the differences between inhalable and total dust samples. (See outputs: presentations.)

## Aim 2: Evaluate Sampler Performance in the Laboratory

An image of the new prototype sampler is shown in Figure 9 alongside the IOM sampler as a reference (sizes are not to scale). The sampler employs a 37-mm filter (similar to the CFC) and is composed of four primary components: inlet cover, inlet, capsule-style filter, and housing with mounting brackets. The inlet (Figure 9b) is designed to aspirate aerosols with the same efficiency as the proposed low velocity inhalability curve at a sampling flow rate of 2 L/min.

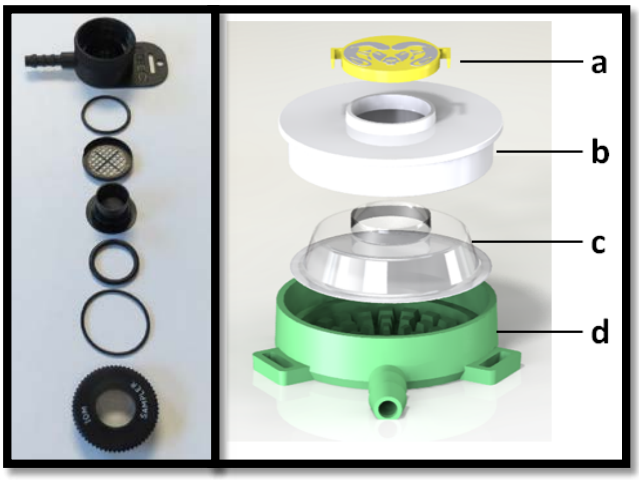



Figure 9. Left – Disassembled IOM Sampler. Right – Exploded view of the new sampling system (a) inlet cover, (b) inlet, (c) capsule and filter, and (d) housing.

The inlet is designed to seal through a "press-fit," eliminating the need for threads or gaskets. Press-fit is a type of sealing that occurs when two surfaces are pressed together and held by material deformation and/or friction. An example of press-fit is the cork in the neck of a bottle; the CFC also seals by using press-fit. The inlet cover (Figure 9a) creates a seal over the inlet to prevent particle loss and contamination during transport/shipping. The inlet cover removes the need for handling the filter outside the laboratory.

A capsule-style filter (Figure 9c) was designed to account for particle losses within the sampler itself (i.e., internal walls losses). The single use capsule consists of thin-film polycarbonate molded using a thermal vacuum-forming technique (Klein, 2009). The outer ring of the capsule contains a 2 mm flange that mates with the outer diameter of the sampling filter; the two components are designed to be weighed (or chemically analyzed) together. In this regard, the capsule may be sealed to the filter using the compressive force of the inlet or chemically bonded to the filter surface using toluene as a welding reagent. This configuration also minimizes cross-contamination as all parts are disposable.

The capsules can be bonded to numerous filter media (Figure 9c), which allows them to be tailored for different analyses. Filter media that have been successfully bonded to the capsules include glass fiber, quartz, mixed cellulose ester, and polytetrafluoroethylene (PTFE/Teflon). Theoretically, a bonded capsule and filter could be disassembled, but this is impractical in most cases. The low cost and disposable nature of the capsules makes single use most appropriate. The capsule design can be applied to measurements beyond simple gravimetric analysis. For example, chemical and biological analyses can be conducted through typical solvent rinse/extraction techniques. As the applicability of rinse/extraction techniques depends on the composition of the sample, further development of such techniques for the new capsule is the subject of ongoing research and testing.

The housing (Figure 9d) was also designed for injection molding using conductive thermoplastic. The base of the housing contains a series of raised ridges to distribute airflow evenly across the sampling filter. The housing contains a hose barb for connection to a personal sampling pump, oriented so the sampler lays flat against the worker's torso, and external brackets for mounting within the worker's breathing zone. Additional details are given in L'Orange et al. (2016).

*Sampling Efficiency*

The sampling efficiency of the new inhalable sampler was found to be within ±13% of the proposed low velocity inhalability criterion for the four smaller particle sizes tested (Figure 10). Both the IOM and the new sampler substantially over sampled at the larger particle sizes (74 μm and 89.5 μm), which were only evaluated at the lower wind speed of 0.1 m/sec.

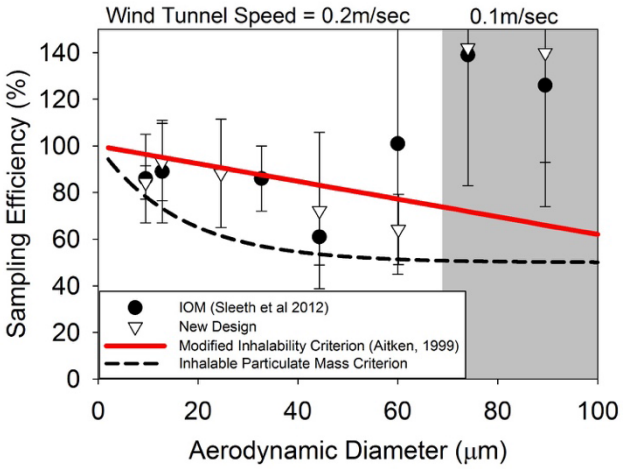



Figure 10: Sampling efficiency of capsules compared to prior studies and the modified inhalability criterion. Error bars represent pooled variance of replicate tests.

*Wall Deposition*

A substantial percentage (60.2% ± 11.2%) of the large particle sizes from the polydisperse microspheres were collected on the interior of the capsule compared to the filter itself (Figure 11). Particle deposition on the walls of the internal capsule was uniformly distributed along the circumference of the internal cap walls. The majority of the particles deposited along the exterior inlet lip that protrudes outwards from the capsule (i.e., the leading edge of the inlet). The size distribution of particles deposited on the internal walls (count median diameter GM = 49 μm; GSD = 1.5) was similar to that on the filter (GM = 58 μm; GSD = 1.4). Size distributions along the interior of the internal cap were similar. The comparatively broader distribution (GSD = 1.5 vs GSD = 1.4) may be a result of multiple phenomena such as static charge and particles bouncing from the filter.

*Capsule Stability and Limit of Detection*

The capsule and filter assemblies conditioned at room temperature (20 °C) reached equilibrium in approximately 65 days, with the majority of mass change occurring in the first week. Capsules and filter assemblies conditioned at elevated temperature (70 °C) required only 25 hr to reach equilibrium. The decrease in equilibration time at elevated temperature supports the hypothesis that toluene evaporation was the major cause of the mass drift. The limit of detection, i.e., the smallest collected mass that can be differentiated from the mass of the capsule and filter assembly after the toluene had fully evaporated, for the six filter-capsule assemblies tested ranged from 7 to 14 μg.

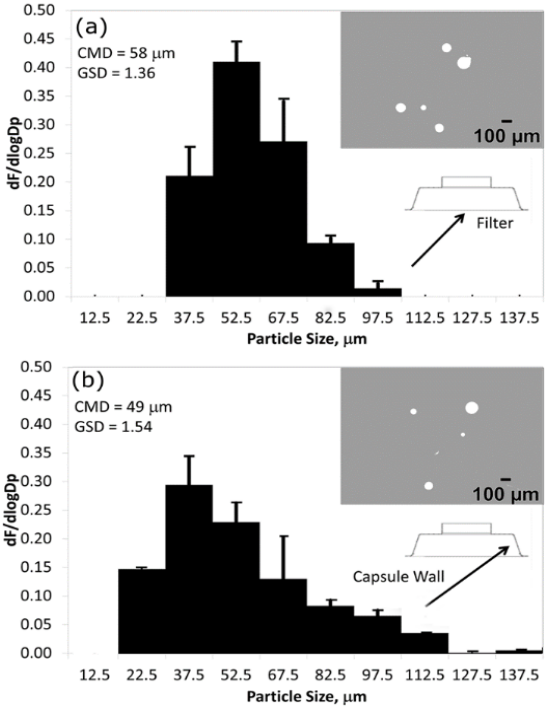



Figure 11: Size distribution of particles collected on the (a) filter and (b) interior capsule walls. The plots represent the size distribution of particles collected on the walls and filter. The y-axis is the log-transformed fraction of particles in each histogram bin.

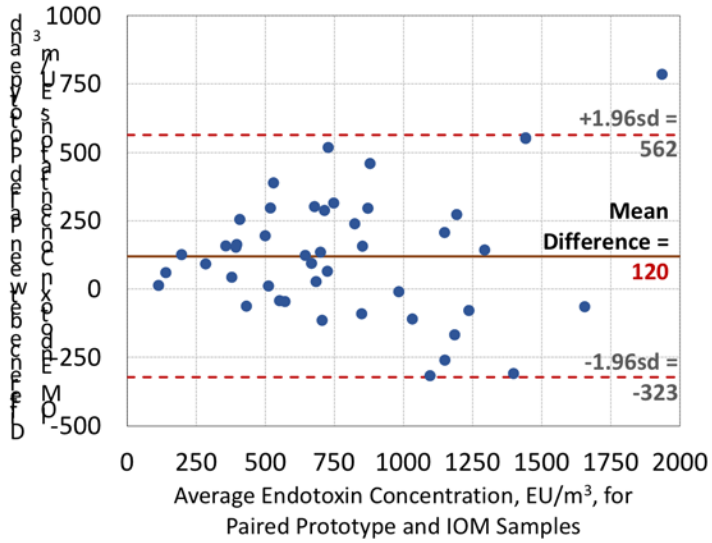
## Aim 3: Validate Sampler Performance in the Field

*Iowa #1: Swine Barn Area Sampling*

Over the three-month winter period in the swine barn, IOM and prototype samples were available for 36 paired dust and 44 paired endotoxin samples. The inhalable dust concentrations were approximately five times that of paired respirable samplers ($p<0.001$, paired t-test), demonstrating that a significant proportion of this dust had particles substantially larger than 10 μm, that is, was predominantly inhalable. The mean concentration of the prototype dust concentrations was 5% below that of the IOM sampler, representing a mean difference of only 0.03 mg/m$^3$, likely insignificant to the quantification of health risk. The range of concentrations in this study ranged up to 1.5 mg/m$^3$.

However, in analyzing these same samples for endotoxin on the collected inhalable dust, we identified that the endotoxin concentrations were nearly 18% higher (120 EU/m$^3$) using the prototype sampler (Figure 12). Based on similarities in gravimetric concentrations, the increased endotoxin in the prototype was likely due to differences in extraction methods and not the sampling efficiency. We reported that the new prototype capsules were soaked with the endotoxin solution, but the rigid internal capsule of the IOM allowed only rinsing to extract wall deposits for analysis. This may indicate that current estimates of endotoxin concentrations from IOM samplers might underestimate exposures. However, endotoxin concentrations did not exceed 1750 EU/m$^3$ in any sample, which is lower than reported in other agricultural operations. (Additional details in Anthony *et al.* 2017.)

Figure 12: Illustration of endotoxin comparison between prototype sampler and IOM, from 24-hour area samples in a swine production operation.



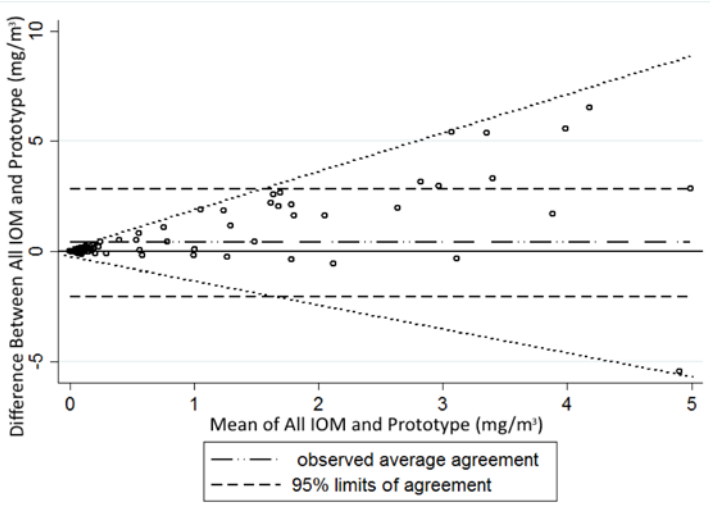

Practical issues associated with deploying the prototype monitors in this study identified difficulties in obtaining the desired 10 L/min flow rate with current personal sampling pumps, even those claiming to perform at 10 L/min. The prototype was redesigned, particularly in the backup pad section, to eliminate the need for using cellulose pad behind filter media in later rounds of field testing.

*Utah #1: Smelter Operation*

A total of 35 side-by-side personal samples were collected from furnace room workers at a metal smelter during two winter months. Jobs included: flash smelting tappers, boiler workers, flash converting tappers, and measurers. For the 35 paired samples, four had no metals detected on either sampler. The prototype sampler had 31 sampling events with concentrations above the LOD, and the

prototype had only 29. Workers had positively identified exposures to: beryllium (4 prototype, 3 IOM), chromium (20 prototype, 11 IOM), manganese (31 prototype, 29 IOM), and nickel (31 prototype, 28 IOM). The prototype sampler was identified as improving the ability to measure above the LOD for manganese and chromium (p=0.024, $\chi^2$) but not other metals. Biases in concentrations were negligible for arsenic (0.00 mg/m$^3$), cadmium (-0.003), and lead (0.01) concentrations. However, inhalable dust and copper concentrations were significantly larger for the IOM than for the prototype (Figure 13). It is important to note that biases may be related to concentration differences between shoulder, and difficulties obtaining weight-stable MCE samples for both IOM and the prototype may have affected the strength of these findings.

Figure 13: Concentration comparisons of inhalable dust, arsenic, cadmium, copper and lead. Differences may increase with increasing concentration.

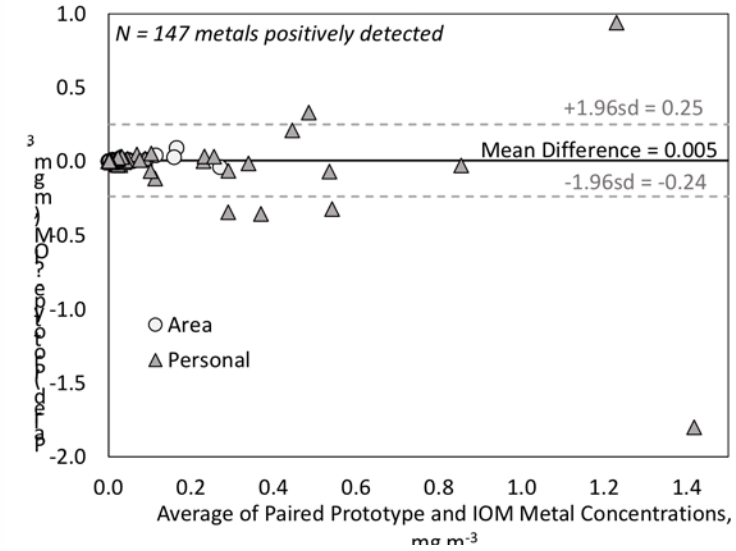



*Iowa #2: Metals operations*

Similar to the smelter study, workplace sampling included a diverse metal species in this study. However, these samples were collected on same shoulder, as shown in Figure 4, to eliminate the potential positioning bias that may have contributed to difficulties in the smelter worker study. In total, 32 paired samples collected. From these, 147 metals were positively identified on both the prototype and the IOM sampler. Only 17 individual metals were identified on the prototype at the same time that it was *not* detected on the IOM: this did not provide a significant increase in detection using the prototype sampler over the IOM.

Figure 14 illustrates the difference in individual metal concentrations between the paired samples plotted by the mean metal concentration reported for each paired sample. The mean difference was insubstantial (0.005 mg/m$^3$) and with moderately small variance. However, two personal samples were identified as extreme outliers, with differences of +1 to -1.8 mg/m$^3$ between samplers for two *personal* measures. The prototype oversampled relative to an IOM during a grinding task (iron) and understampled during metal pouring (zinc). *Removing these two extremes* yielded a mean difference between sampler concentration ***of 0.10 and a 2σ difference of 0.19 mg/m$^3$***. Metal concentrations were neither normally nor log-normally distributed.

Figure 14. Bland-Altman plot of paired difference by average metal concentration (147 metals detected in 32 paired samples)



Regression was used to quantify the mass concentration relationships between the two samplers (Table 1). For each case, the intercepts were insignificant and were removed, thereby forcing the intercepts through zero. The estimated slopes were significant, both for the aggregated data (all particle sizes and both personal and area samples) and for sub-groupings of this data set. The only time that the slope was not significantly different from unity was when both samplers were used *as area samplers* (prototype = 1.05 IOM). When used as area samplers, the prototype sampler identified metal concentrations that were no different than those in the IOM ($\beta$=1.05). This confirmed the previous swine barn study (Iowa #1 field study) findings, where the prototype and IOMs performed similarly when deployed as area samples, with confirmation of large particles in the room.

Table 1. Regression equations to relate metal concentrations between prototype and IOM sampler pairs, fitting the equation: *Prototype* = *Intercept* + $\beta$ *(IOM*).

| Grouping | N | Max mg $m^{-3}$ from IOM | $\beta$ in: Prototype = $\beta$ IOM | C.I. ($\beta$) | Adj. $R^2$ |
|---|---|---|---|---|---|
| All samples | 146 | 2.31 | 1.44 | 1.26 – 1.61 | 0.64 |
| Personal | 92 | 2.31 | 1.45 | 1.22 – 1.68 | 0.63 |
| Area | 54 | 0.29 | **1.05** | 0.97 – 1.13 | 0.93 |
| Small | 65 | 2.31 | 0.81 | 0.76 – 0.87 | 0.93 |
| Large | 81 | 0.78 | 1.78 | 1.52 – 2.04 | 0.68 |

However, when used as *personal samplers*, the prototype sampler appears to have *oversampled*, relative to the IOM, by a factor of 1.45. For small particles, the slope was significantly less than unity, indicating that the *prototype sampled LESS efficiently than the IOM* when particles were presumed to be more aligned with respirable range, but with increased particle size, the prototype appears to have *oversampled* compared to the IOM, by 1.5 to as much as 2 times. Over all samples for which metals were identified, individual metal concentrations in the prototype sampler were 1.44 times that of the IOM.

It is also important to note that this study also had difficulties achieving the target 10 L/min over full-shift monitoring. Although the prototype sampler design eliminated the need to include a backup cellulose pad in the prototype filter holder, the pressure drop needed to achieve even 8 L/min caused both the Leland Legacy (SKC Inc.) and Gillian 12 (Sensidyne Inc.) pumps to drain batteries over 4 hours. While filters used in both samplers were mixed cellulose ester, necessary for subsequent metals analysis, the IOM used traditional 0.8 $\mu$m pore sized MCE but the prototype used 8 um pore size (Sterlitech) to achieve the high flow rate through the sampler.

*CSU #1: Dairy Operations*

Comparisons between the prototype and CFC sampler for dust mass and endotoxin concentrations are shown as box-whisker plots in Figures 15a and 15b, respectively. Exposures tended to be lognormally distributed for both mass and endotoxin concentrations, spanning nearly two orders of magnitude in variability. The prototype sampler measured higher concentrations that the CFC in both cases. Concentrations were, on average, 1.6 and 2.8 times higher for the prototype sampler compared to the 37-mm CFC sampler for mass and endotoxin concentrations, respectively.

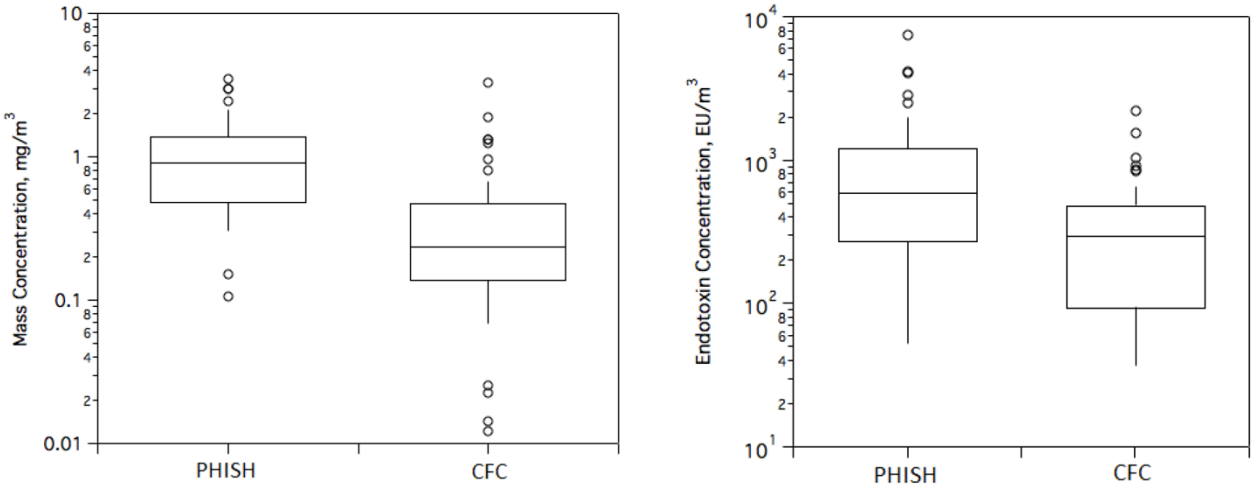



Figure 15. Box-whisker plots of (A) dust and (B) endotoxin concentrations measured across four Colorado dairies using the prototype (PHISH) and 37-mm closed face cassette sampler (CFC).

Mass and endotoxin concentrations were moderately correlated between the two sampler types (Figure 16). The lack of agreement between these two samplers (both in sample mass and correlation) is expected, because aerosol size distributions are known to extend well above 20 μm, which is the approximate size at which the CFC device begins to under-sampler particles.

Differences in baseline cytokine levels were identified by smoking, gender, and whether the worker lived on-site. Current and ex-smokers had slightly higher baseline levels of IL1-β, IL-6, and TNF-α

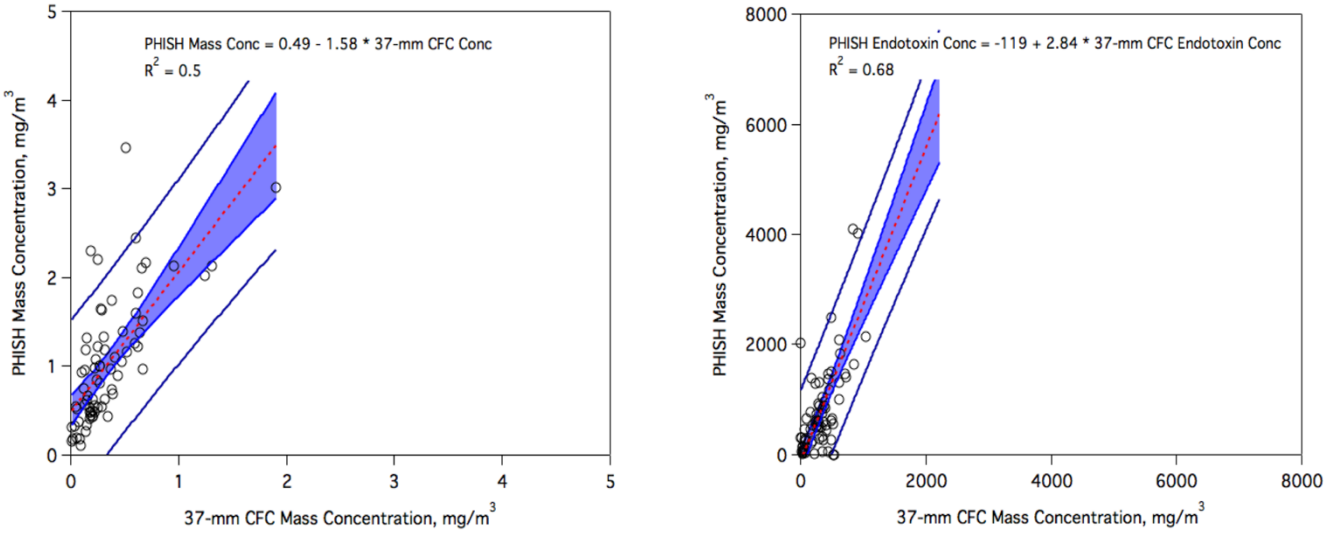



Figure 16. Linear regressions for (A) dust and (B) endotoxin concentrations measured across four Colorado dairies for the prototype (PHISH) vs. the 37-mm closed face cassette sampler (CFC).

compared to non-smokers, but were not significant (P = 0.28). Workers who lived off site (not on a farm) had slightly higher baseline levels of all cytokines, but again were not significantly elevated (P = 0.43). In general, women had lower baseline cytokine levels compared to men, and a more substantial increase in cytokine levels after one day of exposure.

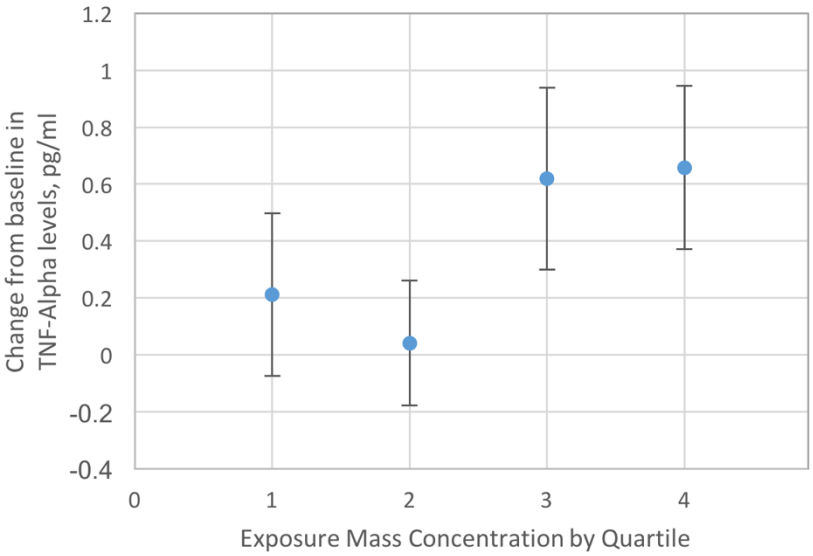



Figure 17. Change from baseline in TNF-α levels measured in nasal lavage vs. dust exposure quartiles for dairy workers. Error bars delineate on standard devation.

TNF-α levels were significantly associated with the difference in inhalable and total mass concentration, dairy, job task, the interaction between dairy and job task. Shown in Figure 17 are levels of TNF-α present in nasal lavage samples arranged by exposure quartiles for these workers. Analyses of the cytokine and pulmonary function data are ongoing as of the writing of this final report. A manuscript describing these results is also currently in preparation.

## Conclusions

Airborne dusts that can be inhaled and deposited anywhere within the respiratory tract are termed "inhalable dusts," or the "inhalable fraction" of aerosols. Exposure to inhalable dust places a tremendous burden on the health of our nation's workforce, with costs estimated at 7 billion dollars per year in the U.S. alone. Every NORA sector contains workplaces where exposure to inhalable aerosols has been associated with both clinical diagnosis and sub-clinical markers of respiratory disease.

The most common method in the U.S. to assess exposures to particles larger than 10 μm relies on the 37-mm closed-face cassette (CFC) sampler. This sampler does not capture an inhalable fraction of aerosols, since large particles (>20 μm aerodynamic diameter) will not penetrate the sampler inlet in the same way as they are inhaled through the mouth and nose of a worker. As such, the CFC under-samples particles, resulting in an underestimate of inhaled dose. Alternative samplers have been designed to capture an inhalable fraction, namely the IOM and the Button samplers. However, these samplers are expensive (hence, non-disposable), prone to contamination, and difficult to operate – limitations that have prevented their adoption by most occupational hygienists. Furthermore, recent scientific evidence indicates that these samplers do not adequately capture an inhalable fraction for typical *low-wind* conditions (<0.3 m/s) that exist in a majority of industries.

This project proved that a low-cost, disposable sampler for inhalable aerosol could be developed that meets the needs of the industrial hygiene community. Both computational modeling and experimental evidence confirmed that the new sampler could meet desired performance metrics at flow rates of 2 and 10 L/min, making the sampler more versatile than its CFC counterpart. Laboratory testing demonstrated that the new sampler matches closely to the performance of current 'gold-standard' methods (i.e., the IOM) while also adhering to published performance criteria for inhalable aerosol sampling.

Multiple field tests of the new sampler, when co-located with existing standard methods, confirmed the results of the laboratory testing while also demonstrating improvements in the new technology related to cost, versatility, and ease-of-use. Further, markers of upper respiratory inflammation in dairy workers were associated with exposures to organic dusts and endotoxin when exposures were assessed using the new sampler.

# Section 2 - Publications

## Publications – Peer Reviewed

1. Anthony TR, Cai C, Mehaffey J, Sleeth DK, Volckens J: [2017] Performance of a Prototype High-Flow Inhalable Dust Sampler in a Livestock Production Building. *Journal of Occupational and Environmental Hygiene*, 14(5):313-322. *[PMC27792469]*
2. Stewart J, Sleeth D, Handy R, Pahler L, Anthony T, Volckens J: [2017] Assessment of increased sampling pump flow rates in a disposable, inhalable aerosol sampler. *Journal of Occupational and Environmental Health*, 14(3):207-213.
3. Anthony TR, Sleeth DK, Volckens J: [2016] Sampling efficiency of modified 37-mm sampling cassettes using computational fluid dynamics. *Journal of Occupational and Environmental Hygiene*, 13 (2):148-158. *[PMC4706812]*
4. L'Orange C, Anderson KR, Sleeth D, Anthony TR, Volckens J: [2016] A simple and disposable sampler for inhalable aerosol. *Annals of Occupational Hygiene*, 60 (2):150-160. *[PMC4753567]*

## Thesis/Dissertations

1. Tompkins AV: [2017] Evaluation of a prototype inhalable sampler: Metals Aerosols, MS Thesis, University of Iowa. (Presents only 21 sample pairs of the 32 presented here.)
2. Manning J: [2017] – Comparison of a New Low Cost High Flow Inhalable Air Sampler and the IOM Sampler for Low Contaminant Concentrations, MSOH Thesis Project, University of Utah
3. Shahan A: [2016] – Comparison of a New Low Cost Inhalable Sampler and IOM Sampler for Field Testing of Smelter Workers, MSOH Thesis Project, University of Utah

## Presentations

1. Tompkins A, Anthony TR: [2017] Evaluation of a prototype inhalable sampler: Metal aerosols. American Industrial Hygiene Conference and Exposition, Seattle, Washington. June 7, 2017.
2. Volckens J. [2016] “A 21st Century Toolkit for the Modern Exposure Scientist: Crayons, Paper, and Plastic.” University of Michigan, School of Public Health, April 2016.
3. Volckens J. [2016] Invited Keynote. Occupational Health in the 21st Century: Romance, Separation, Counseling, and Re-Marriage. American Industrial Hygiene Association YUMA Section Annual Meeting, San Diego, CA, January 2016.
4. Anderson KR, Schaeffer J, Mehaffey J, Bradford M, Tryon J, VanDyke A, Reynolds S, Anthony TR, Sleeth D, L’Orange C, Volckens J. [2016] Effect of Inhalable Exposures on Cytokine Levels in Workers in Northern Colorado Dairies. Podium Presentation, American Association for Aerosol Research. Portland OR. October 2016.
5. Anderson KR**,** Schaeffer J, Mehaffey J, Tryon J, VanDyke A, Bradford M, Reynolds S, Anthony TR, Sleeth D, Volckens J. [2015] Inhalable Particle Exposures in Northern Colorado Dairies. Podium Presentation, American Association for Aerosol Research. Minneapolis, MN. October 2015.

6. Volckens J. [2015] Invited Keynote. Occupational Health in the 21st Century: Romance, Separation, Counseling, and Re-Marriage. The Future of Occupational Health Symposium. University of Washington, Seattle, WA, June 2015.
7. L'Orange C, Anderson K, Sleeth D, Anthony TR, Zimmerle K, Miller-Lionberg D, Volckens J: [2015] Development of a Low-Cost Integrated Sampler/Sample Pump for Inhalable Particles. American Industrial Hygiene Conference and Exposition, Salt Lake City, Utah. June 2, 2015
8. Volckens J. [2015] Engineering for Public Health: 19th Century Innovations for 21st Century Problems. Health Canada Symposium. Ottawa, ON. May 2015.
9. Volckens J. [2015] Point-of-Need Monitoring for Environmental Pollutants and Citizen Science. Pittcon Conference and Expo. New Orleans, LA, March 2015.
10. Anthony TR: [2015] Using CFD to understand large particle inhalability. American Industrial Hygiene Conference and Exposition, Salt Lake City, Utah. June 2, 2015.
11. Volckens J. Arts and Crafts for the 21$^{st}$ Century Industrial Hygienist: How Crayons, Paper, and Pencils Can Help Revolutionize Occupational and Environmental Health. AIHA Rocky Mountain Section Fall Technical Conference. Arvada, CO, September, 2014.
12. Volckens J. [2014] Invited Keynote Speaker. 19th century innovations for 21st century exposure science: how crayons, paper and citizen-based science can revolutionize our field. National Environmental Monitoring Conference. Washington, DC, August 2014.
13. Volckens J. [2014] Invited Plenary Speaker. The 8th International Symposium on Modern Principles for Air Monitoring and Biomonitoring. Marseille, France, June 2014.
14. L'Orange C, Anderson KR, Volckens J, Sleeth DK, Anthony TR: A disposable inhalable aerosol sampler designed to fit a 37-mm cassette. American Industrial Hygiene Conference and Exposition, AIHA, San Antonio, Texas. June 2, 2014.
15. Anthony TR, Sleeth DK, Volckens J: [2014] Investigation of 37-mm CFC inlet modifications on the sampling efficiency of inhaled particles. American Industrial Hygiene Conference and Exposition, AIHA, San Antonio, Texas. June 2, 2014.
16. Volckens J. [2014] A Low-Cost, Disposable Sampler for Inhalable Aerosol. Webinar to the DOE Beryllium Health and Safety Committee. October 15, 2014.
17. Sleeth DK, L'Orange C, Volckens J, Anthony TR: [2013] Development of a Disposable Cassette Inlet for Measuring Inhalable Particles, Inhaled Particles XI, British Occupational Hygiene Society, Nottingham, United Kingdom, September 23, 2013.
18. Anthony TR, Sleeth DK, Volckens J: [2013] Sampler efficiencies of 37-mm cassette with inlets modified to collect inhalable particles. Inhaled Particles XI, British Occupational Hygiene Society, Nottingham, United Kingdom, September 23, 2013.

# Section 2 – Enrollment Tables

## Cumulative Inclusion Enrollment Table

This project was reviewed by institutional review boards at each of the three participating universities. Cumulative enrollment across all institutions is provided in the subsequent table, with details of each study enrollment, as indicated:

- Colorado State University: IRB ID#14-5369H, 37 participants enrolled
- University of Iowa: IRB ID#201607782, 20 participants enrolled
- University of Utah: IRB ID#00084001, 11 participants enrolled

**PHS Inclusion Enrollment Report**

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

This report format should NOT be used for collecting data from study participants.

*Study Title (must be unique): Design, evaluation, and validation of a next-generation inhalable aerosol sampler

* Delayed Onset Study? ☐ Yes ☒ No

*If study is not delayed onset, the following selections are required:*

| | | |
|---|---|---|
| Enrollment Type | ☐ Planned | ☒ Cumulative (Actual) |
| Using an Existing Dataset or Resource | ☒ Yes | ☐ No |
| Enrollment Location | ☒ Domestic | ☐ Foreign |
| Clinical Trial | ☐ Yes | ☒ No |

NIH-Defined Phase III Clinical Trial ☐ Yes ☒ No

Comments: These enrollment numbers are from the University of Iowa projects only

| Racial Categories | Ethnic Categories | | | | | | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | Not Hispanic or Latino | | | Hispanic or Latino | | | Unknown/Not Reported Ethnicity | | | |
| | Female | Male | Unknown/ Not Reported | Female | Male | Unknown/ Not Reported | Female | Male | Unknown/ Not Reported | |
| American Indian/ Alaska Native | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| White | 0 | 14 | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 20 |
| More than One Race | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 0 | 14 | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 20 |

Report 1 of 1

**Study Title:** Design and Evaluation of Interventions to Improve Dairy Worker Respiratory Health

**Total Enrollment:** Up to 128 **Protocol Number:** 14-5369H

**Grant Number:** R01OH010295

| **PART A. TOTAL ENROLLMENT REPORT:** | **Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race** | | | |
|---|---|---|---|---|
| **Ethnic Category** | **Females** | **Males** | **Sex/Gender Unknown or Not Reported** | **Total** |
| Hispanic or Latino | 5 | 29 | 0 | 34 ** |
| Not Hispanic or Latino | 2 | 1 | 0 | 3 |
| Unknown (individuals not reporting ethnicity) | 0 | 0 | 0 | 0 |
| **Ethnic Category: Total of All Subjects*** | 7 | 30 | 0 | 37 * |
| **Racial Categories** | | | | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 | 0 |
| White | 3 | 11 | 0 | 14 |
| More Than One Race | 0 | 3 | 0 | 3 |
| Unknown or Not Reported/ Other | 4 | 16 | 0 | 20 |
| **Racial Categories: Total of All Subjects*** | 7 | 30 | 0 | 37 * |

| **PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)** | | | | |
|---|---|---|---|---|
| **Racial Categories** | **Females** | **Males** | **Sex/Gender Unknown or Not Reported** | **Total** |
| American Indian or Alaska Native | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 | 0 |
| White | 1 | 11 | 0 | 12 |
| More Than One Race | 0 | 0 | 0 | 0 |
| Unknown or Not Reported/ Other | 4 | 18 | 0 | 23 |
| **Racial Categories: Total of Hispanics or Latinos**** | 5 | 29 | 0 | 34 |

## PHS Inclusion Enrollment Report

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

**This report format should NOT be used for collecting data from study participants.**

***Study Title (must be unique):** Design, evaluation, and validation of a next-generation inhalable aerosol sampler

* Delayed Onset Study? ☐ Yes ☒ No

***If study is not delayed onset, the following selections are required:***

| | | |
|---|---|---|
| **Enrollment Type** | ☐ Planned | ☒ Cumulative (Actual) |
| **Using an Existing Dataset or Resource** | ☒ Yes | ☐ No |
| **Enrollment Location** | ☒ Domestic | ☐ Foreign |
| **Clinical Trial** | ☐ Yes | ☒ No |

**NIH-Defined Phase III Clinical Trial** ☐ Yes ☐ No

**Comments:** This study includes only those participants from the University of Utah project

| **Racial Categories** | **Ethnic Categories** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Not Hispanic or Latino | | | Hispanic or Latino | | | Unknown/Not Reported Ethnicity | | | **Total** |
| | **Female** | **Male** | **Unknown/ Not Reported** | **Female** | **Male** | **Unknown/ Not Reported** | **Female** | **Male** | **Unknown/ Not Reported** | |
| American Indian/ Alaska Native | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| White | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| More than One Race | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 11 | 0 | 11 |
| **Total** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 11 | 0 | 11 |

**Report 1 of 1**

## Inclusion of Gender and Minority Study Subjects

Please see attached enrollment tables. No females participated in the Iowa study or the Utah study; a total of 7 females participated in the Colorado State University study.

## Inclusion of Children

No children were included in this study as participants were limited to working adults.

## Materials Available for Other Investigators

Prototype samplers have been fabricated and are available for use by other investgators by contacting the investigation team at Colorado State University (john.volckens@colostate.edu).